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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/612,921 | 07/10/2000 | John E. Sims | 03260.0047 | 9162 |

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| EXAMINER | |
|---|---|
| CHERNYSHEV, OLGA N | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1646 | |

DATE MAILED: 02/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/612,921 | SIMS, JOHN E. | |
| | Examin r | Art Unit | |
| | Olga N. Chernyshev | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *58-62 and 65-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-62 and 65-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12/19/03.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Response to Amendment*

1. Claims 63, 64 and 68-78 have been cancelled and claim 62 has been amended as requested in the amendment of Paper filed on December 19, 2003. Claims 58-62 and 65-67 are pending in the instant application.

Claims 58-62 and 65-67 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on December 19, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### *Claim Rejections - 35 USC § 101*

5. Claims 58-62 and 65-67 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in appropriate sections of Papers No. 8, 12, 17 and 21. Briefly, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

Beginning at page 11, last paragraph, of the Response, Applicant submits that "asserted utility that IL-1 delta nucleic acids can be used to distinguish conditions in which the human IL-1 delta gene is rearranged or deleted is specific". Applicant continues with argument that "[t]he specificity of this utility arises from the specific location of the human IL-1 delta gene on chromosome 2" and refers to Declaration of Sims for support of these arguments.

Applicant's arguments and The Declaration of Sims under 37 CFR 1.132 filed on December 19, 2003 have been fully considered but are not deemed to be sufficient or persuasive to overcome the instant rejection for the following reasons.

As it was fully explained in the previous office actions, the employment of DNA sequences of the instant invention as a chromosome marker does not constitute a specific and substantial utility. One skilled in the art readily understands that any naturally occurring DNA has a "specific location" (page 11, last paragraph of the Response) on a specific corresponding chromosome. However, such specificity does not support a specific substantial utility of that DNA. To use the novel polynucleotides of the instant invention "to distinguish conditions in which the human IL-1 delta gene is rearranged or deleted" without knowledge of these conditions in view of the absence of information regarding a specific biological function of IL-1 delta or its specific association with a pathological condition would be equivalent to using them as an object of future research to establish the utility of the IL-1 delta. 35 USC § 101 clearly states that the invention must be useful in currently available form, which precludes any further experimentation to establish the utility of the claimed invention.

Further, there appears to be no disagreement that one skilled in the art could use the instant polynucleotides for *in situ* hybridization with a specific site on human chromosome 2

"without the need for any additional research" (paragraphs 8-11 of the declaration and also reasoning on pages 12-13 of the Response). The skill in the art is high and *in situ* hybridization protocol itself is well known. The main issue at hand, however, remains that since the instant specification, as filed, does not disclose a specific condition or "conditions associated with rearrangement or deletion of 2q11-12" (top at page 13 of the Response), hybridization of polynucleotides of SEQ ID NO: 3 to human chromosome 2 is not particularly useful. One skilled in the art readily understands that the instant nucleic acids could be used as specific markers for a certain abnormality only if a specific mutation in 2q11-12 region is disclosed as being associated with such an abnormality.

A specification can meet the legal requirements of utility and enablement for a new polynucleotide as long as the specification discloses at least one credible, specific and substantial asserted utility for the new polynucleotide, or a well-established utility for the claimed polynucleotide would be *prima facie* obvious to the skilled artisan. A hypothetical example may serve to clarify. For example, a hypothetical specification discloses that a claimed polynucleotide is presented in a mutated form in colon cancer and in normal form in healthy colon tissue. The hypothetical specification does not disclose the biological activity of the polypeptide encoded by the polynucleotide. The claimed polynucleotide in the hypothetical example would not be rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as it has utility and is enabled as a colon cancer marker. However, such is not the fact pattern here. The instant specification discloses that the human IL-1 delta gene maps to chromosome region 2q11-12 and hypothesizes that the detection of claimed polynucleotides can be used for the diagnosis of physical abnormalities associated with rearrangements in that region. However, there is no

disclosure of any particular disease or pathological condition, which are specifically associated with such rearrangement. Therefore, one skilled in the art readily understands that although hybridization of the instant polynucleotides to 2q11-12 chromosome region in case of patients described in publications of Mu et al. and Glass et al. (pages 13-15 of the Response and paragraphs 12-20 of the Declaration) could establish sequential aberrations, one clearly would not know how to interpret without first making a substantial research contribution in order to discover a clear correlation between a physical abnormality and a mutated form of IL-1 delta polynucleotide.

Thus, it can be concluded that at the time of filing Applicant's invention was incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful, therefore, the instant rejection is maintained.

***Claim Rejections - 35 USC § 112***

6. Claims 58-62 and 65-67 stand rejected under 35 U.S.C. 112, first paragraph because the instant specification does not disclose specific, substantial and credible utility of the claimed isolated nucleic acids, then one skilled in the art clearly would not know how to use the claimed invention.

7. Claims 60-61 and 65-67 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. See reasons of record in appropriate sections of Papers No. 8, No.12, No. 17 and No.21.

Applicant submits that "claims 60 and 61 encompass nucleic acids without regard to the ability of any encoded polypeptide to bind to cells expressing an IL-1 delta receptor. Consequently, none of the Office's reasons for lack of adequate written description is relevant to claims 60 and 61" (page 17, first paragraph of the Response). This argument has been fully considered but is not deemed persuasive for the reasons that follow.

As fully explained in previous office actions, the instant specification, as filed, describes only a nucleic acid of SEQ ID NO: 3. The specification fails to teach or describe any other nucleic acid which lacks the structure of nucleic acid of SEQ ID NO: 3 and has any relevance to IL-1 delta polypeptide. Therefore, it can be concluded that the instant specification fails to describe the entire genus of nucleic acids, which are encompassed by these claims, such as 30 and 60 contiguous nucleotide fragments, as recited in claims 60-61, as well as sequences 95%, 98% and 99% identical to SEQ ID NO: 3, as recited in claims 65-67, and, thus, lacks the written description of the claimed nucleic acids.

***Claim Objections necessitated by amendment***

8. Claim 65 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 65, as amended, depends from claim 62, which is limited to a nucleic acid molecule that hybridizes to DNA comprising sequence of SEQ ID NO: 3, while claim 65 recites a broader molecular embodiment of a sequence that is 95% identical to SEQ ID NO: 3. Therefore, claim 65 can be infringed by a nucleic acid, which does not infringe claim 62. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in

independent form. Applicant should note the "Infringement Test" for dependent claims in MPEP § 608.01(n). The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. A proper dependent claim shall not conceivably be infringed by anything, which would not also infringe the basic claim. In the instant case, the nucleic acid claims could be infringed without infringing the claims from which it depends, i.e. the protein claims. Therefore, they are improperly dependent and should be rewritten in independent form.

***Conclusion***

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. OC

JOHN ULM
PRIMARY EXAMINER
GROUP 1800